DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 23, 2015

FineMEC Company, Ltd.
% Shin Kuk Yoo
LSK Biopartners Incorporated
8 East Broadway, Suite 611
Salt Lake City, Utah 84111

Re: K143666
Trade/Device Name: Noblex Long Pulse Alexandrite Laser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: March 12, 2015
Received: March 20, 2015

Dear Shin Kuk Yoo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143666

Device Name
Noblex Long Pulse Alexandrite Laser

Indications for Use *(Describe)*

The Noblex Long Pulse Alexandrite Laser is indicated for stable long-term or permanent hair reduction. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime. It is used for all skin types (Fitzpatrick I -VI) including tanned skin. It is also indicated for the treatment of benign vascular lesions, benign pigmented lesions and wrinkles.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Prepared date: Mar. 5. 2015

New Device: Noblex Long Pulse Alexandrite Laser

1. Submitter and US Official Correspondent

Submitter: FineMEC Co., Ltd.
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Contact: Mr. Ghun Hee Lee (General Manager)
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US Official Correspondent: Shin Kuk Yoo, Consultant
Telephone No.: 714-313-7442
Fax No.: 801-303-7455
Email: skyone@LSKBioPartners.com

2. Device Information

Proprietary/Trade Name :	Noblex Long Pulse Alexandrite Laser
Common/Usual Name:	Medical Laser System
Classification Name:	Instrument, Surgical, Powered, Laser
Device Class:	21 CFR 878.4810
	GEX
	Class II

3. Description of Device

The Nobelx Long Pulsed Laser system produces a pulsed beam of coherent near infrared (755nm) light. This beam is directed to the treatment zone by fiber optic coupled to hand-piece. When the beam contacts human tissue, the energy in the beam is absorbed, resulting in a very rapid highly localized temperature increase to the target chromospheres such as Hair removal and Pigment treatment. This increases localized temperature of the chromospheres to smaller particles.

By directing the beam onto specific tissue locations, using different hand-pieces, and controlling the treatment fluence, the intensity of the temperature of the target can be varied. The physician can optimize the effect for different applications by controlling the energy of the laser pulse and the spot size of the treatment beam. This equipment is composed of the main body and a hand-piece which is an irradiation device and as an accessory part, protective goggles for protection of the worker.

Operation principle: This equipment is controlled by a micro processor interfaced to a LCD touch screen control panel. The computer controls start and stop of the treatment. When the key switch of the system is turned clockwise, the main power will be inputted, which will be conveyed to the hand piece through the control board.

Meanwhile, the control board connected to the touch screen is connected to the lamp of the hand-piece and controls the same, and controls the whole system through the data connected to the touch screen control panel. When the switch of the hand piece is pressed, the lamp will laser.

4. Indications for Use

The Noblex Long Pulse Alexandrite Laser is indicated for stable long-term or permanent hair reduction. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.

It is used for all skin types (Fitzpatrick I -Ⅵ) including tanned skin. It is also indicated for the treatment of benign vascular lesions, benign pigmented lesions and wrinkles.

5. Performance Testing

The Noblex Long Pulse Alexandrite Laser is required to conform and does conform to the laser performance standards as follows;

1. EN 60825-1:2007, Safety of laser products-Part 1: Equipment classification and requirements
2. EN 60601-2-22: 1996 Medical electrical equipment- part 2: particular requirements for the safety of diagnostic and therapeutic laser equipment.
3. EN 60601-1: 2006 Medical electrical equipment – Part 1 : General requirements for basic safety and essential performance
4. EN 60601-1-2: 2007 Medical electrical equipment – Part 1-2 : General requirements for basic safety and essential performance- Collateral standard : Electromagnetic compatibility- requirements and tests

6. Substantial Equivalence

Substantial Equivalence for the Noblex Long Pulse Alexandrite Laser is based in its similarities in indication for use, design features, operational principles and material composition when compared to the predicate devices cleared under the following submissions:

- K034030 - Cynosure Apogee Elite Laser, Manufactured by Cynosure, Inc.
- K024335 - GentleLASE Family of Laser Systems, Manufactured by Candela Corporation

7. Conclusions

Based on the technical comparisons between the Noblex Long Pulse Alexandrite Laser and the predicate lasers above, these devices are Substantially Equivalent.